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Virginia Tuberculosis Control Laws

GUIDEBOOK

Virginia Tuberculosis Control Laws Guidebook

Outline/Table of Contents



2 Introduction

- About the Virginia Tuberculosis Control Laws Guidebook
- The Role of the Division of Tuberculosis
- A Note on Documentation
- Disclaimer



4 Overview of Tuberculosis Laws

- Virginia's TB Control Laws
- The Purpose of the TB Control Laws
- Legal and Clinical Definitions of Active TB Disease
- Legal and Clinical Infectiousness (Table)
- Other Legal Definitions
- Enforcing the VA TB Control Laws
- Rights of People with Active TB Disease
- Immunity from Liability



10 Protecting the Public Health

- Issuing an Examination Request
- Issuing a Counseling Order
- Issuing an Outpatient Treatment Order
- Issuing an Emergency Detention Order
- Court-Ordered Isolation



19 TB Reporting and Planning

- · Reporting Requirements for Physicians and Medical Facilities
- Reporting Requirements for Laboratories
- TB Treatment Plans: Development and Reporting



25 Appendix

- Forms for Physicians and Medical Facilities
- Summary of Individual Rights
- Contact Information
- Resource Listings

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Introduction

About the VA Tuberculosis Control Laws Guidebook

Virginia's Tuberculosis Laws were amended in 2001 in order to better control the spread of tuberculosis and to help prevent the emergence of drug-resistant tuberculosis in the Commonwealth. These laws address the treatment and containment of **active tuberculosis disease** ("active TB disease").

To illustrate the application of these laws, this guidebook is organized into the following sections:

- 1) Introduction
- 2) Overview of Tuberculosis Laws
- 3) Enforcement of TB Control Laws
- 4) TB Reporting and Planning
- 5) Appendix

As the responsibility for successful treatment of any patient with tuberculosis rests with the provider rather than the patient, this VATB Control Laws Guidebook is intended as a resource for Local Health Directors, Heads of Medical Facilities, Nurses, Infection Control Practitioners, and Private Physicians in the Commonwealth of Virginia.



Throughout this guidebook, references are made to particular sections of the *Code of Virginia* (e.g., \S 32.1-50). URLs for these sections of the *Code of Virginia* are listed in the **Overview** section as well as in the **Appendix**.

The Role of the Division of Tuberculosis Control

The Virginia Department of Health Division of Tuberculosis Control (DTC) acts as a liaison between the different entities involved in the implementation of the Virginia TB Control Laws (e.g., local health directors, private physicians, the Commissioner, etc.) and coordinates all actions taken under the enforcement of these laws. The Division of TB Control provides necessary guidance through these processes and should be contacted with all questions regarding the definition and implementation of the Virginia TB Control Laws.

Division of Tuberculosis Control 1500 East Main Street Room 119 Richmond, VA 23219 telephone: 804-786-6251 fax: 804-371-0248

url: www.vdh.state.va.us/epi/tb/

A Note on Documentation

Many of the orders and other actions detailed in this guidebook rely upon documentation—*e.g.*, documenting efforts to counsel a potentially infected person about tuberculosis, documenting a patient's adherence to treatment, etc. While there are no prepared forms or official guidelines for how such documentation is to be maintained (apart from required reporting forms), it is important to understand that this documentation is an integral part of tuberculosis control and is used to support both the patient's treatment as well as the implementation of the Tuberculosis Control Laws.

Disclaimer

Please note that laws and regulations can be changed, revised, or amended at any time. The contents of this guidebook do not take the place of appropriate legal advice. Please consult the current *Code of Virginia* and State Board of Health regulations for up-to-date information. If you have any questions regarding the Virginia Tuberculosis Control Laws, the regulations of the State Board of Health, or their application, you should contact the Virginia Department of Health Division of Tuberculosis Control, or seek the guidance of an attorney.



Overview of Tuberculosis Laws

Virginia's TB Control Laws

The Virginia TB Control Laws can be viewed online:

§ 32.1-48.01	Definitions. http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-48.01
§ 32.1-48.02	Investigations of verified reports or medical evidence; counseling; outpatient and emergency treatment orders; custody upon emergency order. http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-48.02
§ 32.1-48.03	Petition for hearing; temporary detention. http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-48.03
§ 32.1-48.04	Isolation hearing; conditions; order for isolation; right to appeal. http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-48.04
§ 32.1-49.1	Definitions. http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-49.1
§ 32.1-50	Examination of persons suspected of having active tuberculosis disease; reporting; report forms; report schedule; laboratory reports and required samples. http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-50
§ 32.1-50.1	Treatment plan; submission of plan and mediation of disagreements; determination of cure. http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-50.1

The complete *Code of Virginia* is available online: http://legis.state.va.us/codecomm/codehome.htm

The Commonwealth of Virginia State Board of Health Regulations for Disease Reporting and Control web resource: http://www.vdh.state.va.us/epi/regcover.htm

The Purpose of the TB Control Laws

Virginia's TB Control Laws have been amended to address the need for specific and detailed TB control measures. As the likely consequences of failure to deliver successful treatment are drug resistance, continued transmission of *M. tuberculosis*, and, potentially, increasing organ damage and death, these TB control measures are intended to:

- Effectively identify cases of active TB disease as quickly as possible.
- Implement appropriate and immediate treatment for cases of active TB disease.
- Establish legal guidelines under which TB treatment is followed and completed.
- Establish guidelines for timely and efficient reporting of TB cases and lab results.
- Prevent the development and spread of drug-resistant TB.

To meet these goals, the Virginia TB Control Laws empower health authorities to:

- Activate protocols to address the possible threat of TB to the public health.
- Provide appropriate resources to help people with active TB disease follow and complete the prescribed treatment regimen.
- Restrict the movements of individuals with active TB disease who are unable or unwilling to follow instructions and orders issued by the Virginia Department of Health and/or a private physician, in the event that prior legal measures to protect the public health have failed.

Legal and Clinical Definitions of Active TB Disease

This subsection of the VA TB Control Laws Guidebook discusses the differences between the legal and clinical definitions of active TB disease. While legal definitions are used in the execution of the measures of escalating authority (e.g., outpatient treatment order, emergency detention order, etc.), clinical definitions are used during the course of treatment. For the purpose of effectively addressing and controlling active TB disease and protecting the public health, the legal definitions are necessarily more broad than those employed clinically.



Legal Definitions of Tuberculosis (§ 32.1-49.1)

- "Active tuberculosis disease" (also, "active TB disease") means a communicable disease caused by an airborne microorganism and characterized by the presence of either (i) a specimen of sputum or other bodily fluid or tissue that has been found to contain tubercle bacilli as evidenced by culture or other definitive diagnostic test as established by the Commissioner, (ii) a specimen of sputum or other bodily fluid or tissue that is suspected to contain tubercle bacilli as evidenced by smear and sufficient clinical and radiographic evidence of active tuberculosis disease is present as determined by a physician licensed to practice medicine in the Commonwealth, or (iii) sufficient clinical and radiographic evidence of active tuberculosis disease as determined by the Commissioner is present, but a specimen of sputum or other bodily fluid or tissue containing or suspected to contain tubercle bacilli is unobtainable.
- "Tubercle bacilli" means disease-causing organisms belonging to the *Mycobacterium tuberculosis* complex and includes *Mycobacterium tuberculosis*, *Mycobacterium bovis*, *Mycobacterium africanum* or other members as established by the Commissioner.
- "Tuberculosis" means a disease caused by tubercle bacilli.



Clinical Definition of Tuberculosis Disease

Diagnosis of active TB disease is based on history, symptoms, bacteriological studies, radiography, physical findings, and tuberculin skin test results.

A diagnosis of active TB disease may be considered for any patient who has:

- A persistent cough (i.e., a cough lasting for three weeks), or
- Other signs or symptoms compatible with active TB disease (e.g., bloody sputum, night sweats, weight loss, anorexia, or fever).

Active TB disease is strongly suggested by:

- Diagnostic evaluation revealing AFB in sputum,
- · Chest radiograph suggestive of TB, or
- Symptoms highly suggestive of TB.

Culture identification of *M. tuberculosis* in body secretions or tissues renders a definitive diagnosis of active TB disease.



Legal Definition of TB Infectiousness (§ 32.1-50.1.E)

Once established in a person, active tuberculosis disease shall be considered present – and the patient shall be considered infectious – until <u>both</u> of the following:

- The person has received a complete and adequate course of antituberculosis drug therapy as established by the Commissioner in accordance with guidelines developed by the American Thoracic Society and Centers for Disease Control and Prevention;
- Three successive cultures of specimens of sputum or other bodily fluid or tissue collected at intervals of no less than one week, or other definitive diagnostic test as established by the Commissioner demonstrate no viable tubercle bacilli;

or until:

• The Commissioner or his designee determines that the clinical, laboratory, or radiographic evidence leads to a diagnosis other than active tuberculosis disease.



Clinical Definitions of TB Infectiousness

Patients who have suspected or confirmed active TB disease should be considered **infectious** if they:

- a) Are coughing or are undergoing cough-inducing procedures,
- b) Have positive AFB sputum smears, or
- c) Show cavitation on chest radiograph;

and if they

- a) Are not on chemotherapy,
- b) Have just started chemotherapy, or
- c) Have a poor clinical or bacteriologic response to chemotherapy.



Infectiousness appears to decline very rapidly after adequate treatment is started, but how quickly infectiousness declines varies from patient to patient. Decisions about infectiousness should be made on an individual basis.

A patient who has drug-susceptible TB can be considered **non-infectious** and isolation may be discontinued when:

- The patient has been receiving adequate treatment for 2-3 weeks;
- Symptoms have improved (e.g., reduction of cough, resolution of fever); and
- Three consecutive sputum specimens obtained on different days are negative by smear.

Legal and Clinical Infectiousness

This table illustrates the differences between legal and clinical standards of infectiousness and under what conditions the determination of infectiousness can be made. For more information about this distinction, contact the Division of TB Control.

	INFECTIOUSNESS				
EVIDENCE/DETERMINATION	LEGAL STANDARD	CLINICAL STANDARD			
Clinical Suspicion Smear negative Culture negative	Yes The Commissioner may determine that this patient is considered infectious	No			
Clinical Suspicion Smear positive Culture pending	Yes A medical evaluation may determine that this patient is considered infectious	Yes A medical evaluation may determine that this patient is considered infectious			
Smear positive Culture positive	Yes	Yes			
Smear negative Culture positive	Yes	No			



Other Legal Definitions (§ 32.1-48.01)

- "Appropriate precautions" means those specific measures which have been demonstrated by current scientific evidence to assist in preventing transmission of a communicable disease. Appropriate precautions will vary according to the disease. [Note: please contact the Division of Tuberculosis Control or consult the Virginia Tuberculosis Control Manual for detailed information on specific precautions.]
- "At-risk behavior" means engaging in acts which a person, who has been informed that he is infected with a communicable disease, knows may infect other persons without taking appropriate precautions to protect the health of the other persons (e.g., failure to follow a prescribed course of treatment, failure to comply with quarantine recommendations, failure to wear appropriate mask as instructed, etc.).
- "Communicable disease" means an illness of public health significance, as determined by the Commissioner of Health, caused by a specific infectious agent which may be transmitted directly or indirectly from one person to another.

Enforcing the VATB Control Laws

Protecting the Public Health

Virginia's TB Control Laws enable health officials to activate a series of measures of escalating authority. These measures address individuals with active TB disease whose failure to follow treatment puts them at high risk of developing drug-resistance and of transmission to others. Each of these orders is discussed in detail in the following section, **Enforcement of TB Control Laws**:

- An **examination request** may be issued by the local health director, the Commissioner, or the Commissioner's designee.
- A **counseling order** may be issued by the local health director, the Commissioner, or the Commissioner's designee.
- An **outpatient treatment order** may be issued by the local health director, the Commissioner, or the Commissioner's designee. Any disagreement regarding the treatment plan will be resolved by the Commissioner.
- An **emergency detention order** may be issued by the Commissioner.
- While the emergency order is in effect, the Commissioner will prepare for the isolation hearing which may result in **court-ordered isolation**.

Any action the local health director may take may also be initiated by the Commissioner. Determining which of the above measures is to be used must be based on a process that ensures that the needs and the rights of the patient as well as those of the public are met.

TB Reporting and Planning

The TB Control Laws also address the required reporting process for treating physicians, medical facilities, and laboratories. Efficient and prompt reporting of TB cases, treatment information, and laboratory results is a key factor in effective TB control.

For patients undergoing inpatient treatment, the hospital or other health care facility is required to submit a treatment and discharge plan to the local health director for approval. In the case of outpatient treatment, the local health director may request to have the treatment plan submitted.



A treatment plan is required for all patients with confirmed TB disease and those who are suspects. Whenever treatment has been started—even treatment based only on suspicion of active TB disease—a treatment plan must be in place. The treatment plan must be submitted to and approved by the local health director prior to discharge from any medical facility, correctional center, or other similar facility, even for patients who have suspected TB disease.

Rights of People with Active TB Disease

- A person will not be physically forced to swallow medication.
- All warnings and orders will be in a language the person can understand.
- A person subject to a court order has the right to appeal.
- Any action (e.g., a counseling order or order for treatment) will be supported by proper documentation.
- A person subject to a court order has the right to appeal.
- If ordered to appear before the court, the person shall be informed of his/her right to representation by counsel.
- A person who cannot afford legal counsel will have it provided for him or her.
- Neither the Commissioner nor any local health director shall disclose to the public the name of any person reported.

Immunity from Liability (§ 32.1-38)

Anyone making a report under the guidelines of Virginia's TB Control Laws is immune from civil liability or criminal penalty unless he/she has acted with gross negligence or malicious intent. Neither the Commissioner nor any local health director will publicly disclose the name of anyone making such a report or the name of anyone reported.



Protecting the Public Health

Issuing an Examination Request (§ 32.1-50)

Scope

If a local health director suspects that a person has active tuberculosis disease and could endanger the public health, the local health director may issue an examination request. The examination request advises the person to be examined immediately to ascertain the presence or absence of active TB disease.

The person may choose to have this examination performed by a licensed physician at his/her own expense. Prior approval from the local health director must be secured before this examination takes place. The person also has the option of having the examination performed by the local health director at no cost.

Criteria

Prior to issuing an examination request, the local health director must be able to document that:

• The person has or is suspected of having active TB disease, as defined by the VA TB Control Laws.

Elements of an Examination Request

The examination request must contain the following information:

- The name of the person being issued the examination request.
- The basis on which the local health director believes that the person has or is suspected of having active TB disease, as defined by the VA TB Control Laws.
- The medical and legal consequences of failing to be examined.
- The period of time the request is in effect. This time period may not exceed the minimum necessary to make a medical determination of the person's condition.
- Where, when, and by whom the examination for tuberculosis should be performed.

Process Summary

An examination request may be issued by the local health director, who will:

- 1) Determine if the necessary criteria for an examination request have been met.
- 2) Call the Division of Tuberculosis Control for guidance and to indicate that this process is underway.
- 3) Write an examination request that includes the required information elements. An examination request form letter is available from the internal DTC website at: http://vdhweb/epi/tb/
- 4) Determine the most effective means of delivering the request. Possible options include registered or certified mail and delivery by local health department staff or state or local law enforcement officials.

5) Follow the reporting guidelines detailed in the next section, **TB Reporting and Planning**. Forms for these reporting procedures are included in the **Appendix**. **Note:** The examining physician who does not find evidence for a positive TB diagnosis in a person under an examination request must still report these findings to the local health director; the appropriate form for this report [Negative Diagnosis Form] is included in the **Appendix**.



If a person with suspected or confirmed active TB disease, as defined by the VA TB Control Laws, fails to comply with the examination request, a counseling order and/or an outpatient treatment order may be issued.

Issuing a Counseling Order (§ 32.1-48.02)

Scope

The local health director may issue a counseling order to any person who has active TB disease as defined by the VA TB Control Laws, who is believed to know that he/she is infected with a communicable disease, and who is engaging in at-risk behavior, thus endangering the public health.

Criteria

Prior to issuing a counseling order, the local health director must be able to document that:

- The person has active TB disease, as defined by the VA TB Control Laws.
- The person is engaging in at-risk behavior.

Elements of a Counseling Order

The counseling order must contain the following information:

- The name of the person being issued the counseling order.
- The basis on which the local health director has determined that the person has or is suspected of having active TB disease, as defined by the VA TB Control Laws.
- The basis on which the local health director believes the person is engaging in at-risk behavior – including inability or unwillingness to follow the prescribed course of treatment.
- The medical and legal consequences of failing to comply.
- Where, when, and to whom the person is ordered to report for counseling.

Process Summary

A counseling order may be issued by the local health director, who will:

- 1) Determine if the necessary criteria for a counseling order have been met.
- 2) Call the Division of Tuberculosis Control for guidance and to indicate that this process is underway.
- 3) Write a counseling order that includes the required information elements. A counseling order form letter is available from the internal DTC website at: http://vdhweb/epi/tb/
- 4) Determine the most effective means of delivering the order. Possible options include registered or certified mail and delivery by local health department staff or state or local law enforcement officials.



Intensive educational efforts must be initiated as soon as the patient is suspected of having tuberculosis. The patient should be given information about tuberculosis and counseled on expected outcomes of treatment, the benefits and possible adverse effects of the drug regimen, methods of supervision, assessment of response, and infectiousness and infection control. The medication regimen must be explained in simple language and must be supplemented by written instructions. Materials should be appropriate for the culture, language, age, and reading level of the patient.

Issuing an Outpatient Treatment Order (§ 32.1-48.02.C)

Scope

The local health director may issue an outpatient treatment order to any person who has active TB disease as defined by the VA TB Control Laws and who is unable or unwilling to adhere to a prescribed treatment regimen, thereby endangering the public health.

Criteria

Prior to issuing an outpatient treatment order, the local health director must be able to document that:

- The person has active TB disease, as defined by the VA TB Control Laws.
- The person has been counseled about the need to complete treatment and about the medical and legal consequences for failing to adhere to treatment.
- The person has refused or failed to adhere to a prescribed course of treatment.
- Despite counseling efforts, the person is engaging in behavior that places uninfected persons at risk.

Elements of an Outpatient Treatment Order

The outpatient treatment order must contain the following information:

- The name of the person being issued the outpatient treatment order.
- The basis on which the local health director believes that the person has active TB disease – include the name of the examining physician and the date of the examination.
- The basis on which the local health director believes the person is unwilling or unable to adhere to a prescribed course of treatment.
- Documented efforts to counsel the person about the need to complete treatment and about the medical and legal consequences for failing to adhere to treatment.
- The basis on which the local health director believes that, despite counseling, the person is engaging in conduct that unreasonably places uninfected persons at risk of contracting TB.
- The course of action being ordered including where and when the person is to report for testing and/or treatment, requirements for Directly Observed Therapy, and mandatory compliance with regular evaluations.
- Notice of legal consequences for failure to comply with the outpatient treatment order.

Process Summary

An outpatient treatment order may be issued by the local health director, who will:

- 1) Determine if the necessary criteria for an outpatient treatment order have been met.
- 2) Call the Division of Tuberculosis Control for guidance and to indicate that this process is underway.
- 3) Write an outpatient treatment order that includes the required information elements. An outpatient treatment order form letter is available from the internal DTC website at: http://vdhweb/epi/tb/

- 4) Determine the most effective means of delivering the order. Possible options include registered or certified mail and delivery by local health department staff or state or local law enforcement officials.
- 5) Follow the reporting guidelines detailed in the next section, **TB Reporting and Planning**. Forms for these reporting procedures are included in the **Appendix**.

Issuing an Emergency Detention Order (§ 32.1-48.02)

Scope

If the local health director determines that a person with active TB disease is engaging in at-risk behavior and poses an imminent threat to the health of others, the Commissioner may issue an emergency order to have that person taken into temporary custody—in the least restrictive, willing facility providing protection of the health of others and appropriate treatment—for a period not to exceed forty-eight hours.



The emergency detention order is the most extreme enforcement of the TB Control Laws to protect the public health. When prior measures have been exhausted, the person with active TB disease is considered a threat to the health of others and his/her situation must be handled as an emergency.



Timeframe for custody

If the specified forty-eight-hour period terminates on a Saturday, Sunday or legal holiday, such person may be detained until the next day which is not a Saturday, Sunday, or legal holiday. (§ 32.1-48.02.D)

Criteria

Prior to issuing an emergency order, the local health director must be able to document that:

- The person has active TB disease, as defined by the VA TB Control Laws.
- The person has been counseled about the need to complete treatment and about the medical and legal consequences for failing to adhere to treatment.
- Despite counseling, the person is engaging in conduct that unreasonably places uninfected persons at risk of contracting TB.
- Medical data demonstrate that the person poses an imminent threat to the health of others.

The local health director must also ensure that <u>one of the following</u> conditions has been met:

- The person has refused or failed to report to the local health department after having been ordered to do so for appropriate outpatient treatment and education (counseling order, outpatient treatment order).
- The person has a documented history of failure to adhere to a prescribed course of treatment.
- The person has indicated that he/she will not comply with the prescribed treatment.

Elements of an Emergency Detention Order

The emergency detention order must contain the following information:

- The name of the person being issued the emergency detention order.
- The basis on which the local health director believes that the person has active TB disease – include the name of the examining physician and the date of the examination.
- The basis on which the local health director believes the person is unwilling or unable to adhere to a prescribed course of treatment.
- Documented efforts to counsel the person about the need to complete treatment and about the medical and legal consequences for failing to adhere to treatment.

- The basis on which the local health director believes that, despite counseling, the person is engaging in conduct that unreasonably places uninfected persons at risk of contracting TB.
- Medical data demonstrating that the person poses an imminent threat to the health of others.

Process Summary

An emergency detention order may be issued by the Commissioner. The Division of TB Control will work closely with the Commissioner to activate an emergency detention order. The local health director also plays an important role in this process.

- 1) The local health director will consult with the Department of TB Control to determine that the criteria for the emergency detention order have been met.
- 2) The Division of TB Control must be contacted immediately.
- 3) The Division of TB Control will work with the Commissioner and the Attorney General to set the process for the emergency detention order into motion.
- 4) The local health director will send to the Division of TB Control all relevant documentation (*e.g.*, clinical information, documented counseling efforts, etc.) to assist the Attorney General in preparing the case.
- 5) In consultation with the local health director and the Attorney General, the Division of TB Control will write the emergency detention order, including necessary information elements. This order will be presented to the Commissioner for his/her signature. An emergency detention order form letter is available from the internal DTC website at: http://vdhweb/epi/tb/
- 6) The local health director will secure a place of confinement for the person who is the subject of the emergency detention order.
- 7) The local health director will alert local law enforcement to be prepared for delivering this forthcoming order. See note below regarding custody.
- 8) Any questions or concerns regarding the legal basis for the comissioner's order or its enforcement should be directed promptly to the Office of the Attorney General.
- 9) While the emergency detention order is in effect, the Commissioner will proceed to prepare for the isolation hearing. This process is explained in the next sub-section, **Court-Ordered Isolation**.



State and local law-enforcement officers are authorized to take custody of the subject of such emergency order immediately upon issuance of the emergency order by the Commissioner.

(§ 32.1-48.02.E)

(§32.1-50.1.D)



The Commissioner may also issue an emergency detention order for a person with active TB disease upon release from an inpatient treatment facility or a state or local correctional or detention facility. This emergency detention order will be issued if the person with active TB disease indicates an unwillingness to comply with the prescribed treatment plan or exhibits noncompliant behavior.

Court-Ordered Isolation (§ 32.1-48.04)

Scope

Once an emergency detention order has been issued by the Commissioner, he/she will proceed to prepare for the isolation hearing. The general district court in the county or city in which the person resides will determine during the isolation hearing whether isolation is necessary to protect the public health.

Criteria (§ 32.1-48.04.B)

An isolation order may be issued upon a finding by the court that the following conditions are met:

- The person is infected with a communicable disease.
- The person is engaging in at-risk behavior.
- The person has demonstrated an intentional disregard for the health of the public by engaging in behavior which has placed others at risk for infection.
- There is no other reasonable alternative means of reducing the risk to public health.



Note on Individual Rights

Isolation orders shall not be renewed without affording the person all of the following rights:

- Right to appeal an isolation order to the circuit court in the jurisdiction in which he/she resides must file within thirty days.
- An appeal of isolation shall be given priority over all other pending matters before the court and shall be heard as soon as possible.
- An order continuing the isolation will only be renewed if the conditions under which an isolation order can be issued are still met at the time the appeal is heard.
- If the person is not represented by counsel, the judge will appoint an attorney-at-law, to be paid a fee of \$150 and necessary expenses, to represent him/her.
 (§ 32.1-48.04.D)



Orders for isolation in the person's home or another's residence may be enforced through the use of electronic devices. Orders for isolation may include additional requirements such as participation in counseling or educational programs. The court may, upon finding that the person no longer poses a substantial threat to the health of others, issue an order solely for participation in counseling or educational programs. (§ 32.1-48.04.C)

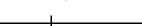


The order for confinement is required to provide the least restrictive confinement; provided, however, that such a detention facility may be a jail or prison if no less restrictive confinement is available or suitable.



The isolation hearing must be held within forty-eight hours of the execution of any temporary detention order.

The isolation hearing shall be held within forty-eight hours of the execution of any temporary detention order issued or, if the forty-eight-hour period terminates on a Saturday, Sunday, legal holiday or day on which the court is lawfully closed, the isolation hearing shall be the next day that is not a Saturday, Sunday, legal holiday or day on which the court is lawfully closed. (§ 32.1-48.04.A)





Isolation order will be valid for no more than 120 days.

An isolation order in the person's home or another's residence or an institution or other place shall be valid for no more than 120 days, or for a shorter period of time if the Commissioner or the Commissioner's designee, or the court upon petition, determines that the person no longer poses a substantial threat to the health of others. (§ 32.1-48.04.C)

TB Reporting and Planning

Reporting Requirements for Physicians and Medical Facilities (§ 32.1-50)

Scope

The private physician who diagnoses or treats a patient for active TB disease on an outpatient basis is required to report the information below to the local health director—or to another professional employee of the local health department—within 24 hours by the most rapid means available, preferably that of telecommunication (e.g., telephone, telephone transmitted facsimile, telegraph, teletype, etc.). The head of a medical care facility—or his/her designee—providing inpatient or outpatient diagnosis or treatment for active TB disease is required to make this same report within the same timeframe and by the same means mentioned above.

Process Summary (§ 32.1-50.B)

There are three elements to this reporting process:

- 1) Initial report [Epi-1] to be completed when there are reasonable grounds to believe that a person has active TB disease.
- 2) Secondary report [2001A-TB-002] to be completed simultaneously with or immediately following the initial report.
- 3) Subsequent reports [2001A-TB-003] to be completed when:
 - there has been a change in regimen;
 - if there is a suspicion of treatment failure;
 - when ceasing treatment for active TB disease;
 - any information required by the initial or secondary reports that was not available at the time of reporting becomes available or has since been revised.

For the purpose of these reports, cessation of treatment will be inferred from the following events: (§ 32.1-50.B)

- The patient fails to keep a scheduled appointment for treatment.
- The patient relocates without taking steps to transfer care.
- The patient discontinues care either upon or against the advice of the treating physician.

1. Initial Report (§ 32.1-50.C)

The initial disease report to the local health director by the diagnosing or treating physician, or by the diagnosing or treating medical care facility, must include the following elements:

- The patient's name.
- The patient's date of birth.
- The patient's gender.
- The patient's address.
- Pertinent clinical, radiographic, microbiologic, and pathologic reports whether final or pending.
- Any necessary information to locate the patient for follow-up.

See the **Appendix** for the appropriate initial report form [Epi-1].

2. Secondary Report (§ 32.1-50.C)

Coinciding with the initial TB report is the secondary report, which should be filed with the initial report or very shortly thereafter. This secondary report supplements the initial report by providing more detailed clinical and management information:

- Date and results of PPD test
- Date and results of initial and follow-up chest x-rays
- Dates and results of bacteriologic testing
- Start date and doses of TB medications regimen
- Date and results of drug-susceptibility testing
- Patient's HIV status
- Contact screening information

Following the submission of the initial report, the local health director will request this secondary report if it was not submitted at the same time as the initial report. See the **Appendix** for the appropriate secondary report form [2001A-TB-002].

3. Subsequent Reports (§ 32.1-50.D)

Following the initial report to the local health director, subsequent reports are to be made <u>when updated information is available</u>. These reports will provide:

- The patient's updated clinical status.
- Updated bacteriologic and radiographic results.
- An assessment of the patient's adherence to treatment.
- The name of the patient's current provider.
- The patient's current or revised regimen.
- Updated contact information for locating the patient.
- Additional clinical information as it becomes available.

Subsequent reports are required when:

- The patient's regimen changes.
- The patient's clinical status changes (e.g., suspected treatment failure).
- The patient's treatment ceases for reasons given on the previous page.
- There are any other updates on the patient's case.

See the **Appendix** for the appropriate subsequent report form [2001A-TB-003].

Reporting Requirements for Laboratories (§ 32.1-50.E)

Scope

Reporting requirements for laboratories doing business in the Commonwealth ensure that testing for antimicrobial susceptibility is completed on each initial isolate from a patient with active tuberculosis disease.

Laboratories are responsible for reporting results that are diagnostic of or are highly correlated with active TB disease, whether this testing is done in-house or is referred to an out-of-state laboratory.

Elements of Reporting for Laboratories

The reporting requirements for laboratories include the following:

- Results of cultures which are positive for tubercle bacilli.
- Results of smears which are suggestive of tubercle bacilli.
- Results of tests for antimicrobial susceptibility performed on cultures which are positive for tubercle bacilli.

Process Summary

- 1) To fulfill this reporting requirement, the director of the laboratory <u>must</u>:
- Report a positive smear and/or positive culture.
- 2) Additionally, the director of the laboratory is required to do one of the following:
- Submit a representative and viable sample of the initial culture to the Virginia Division of Consolidated Laboratory Services.
- Submit to the local health director a report of antimicrobial drug susceptibilities performed by a laboratory certified by existing state or national agencies to perform such testing.



NOT

When initially reporting a culture which is positive for tubercle bacilli, the director of the laboratory must communicate to the local health director his/her intention to file a written report of antimicrobial susceptibilities in lieu of submitting a culture sample.

TB Treatment Plans: Development and Reporting (§ 32.1-50.1)

Scope

The physician who is treating a patient with active tuberculosis disease on an outpatient basis, and the head of a medical care facility providing inpatient or outpatient treatment for active TB disease, must work with the patient to develop an individualized, written plan of treatment. The treating physician or the head of the medical care facility is required to maintain written documentation of the patient's adherence to the treatment plan.

A treatment plan is required for all patients with confirmed TB disease and those who are suspects. Whenever treatment has been started—even treatment based only on suspicion of active TB disease—a treatment plan must be in place. The treatment plan must be submitted to and approved by the local health director prior to discharge from any medical facility, correctional center, or other similar facility, even for patients who have suspected TB disease.

Elements of a Treatment Plan (§32.1-50.1.A)

As it is important that patient-centered programs be developed to assess each patient's needs so that therapy can be completed, this treatment plan must:

- Be tailored to the patient's medical and personal needs.
- Be maintained and updated as needed.
- Identify the method for effective treatment.
- Identify the method for prevention of transmission.

This treatment plan must specifically include:

- The patient's verified address.
- The name of the medical provider who is responsible for treatment.
- The planned course of antituberculosis drug therapy.
- The estimated date of completion of treatment.
- The means of ensuring successful completion of treatment.

The treatment plan should be updated monthly in conjunction with consultation with the patient. This monthly review of clinical progress will allow an evaluation of the response to therapy and identify adherence problems.

A template for the Treatment/Discharge Plan [2001A-TB-004] can be found in the **Appendix**.



The use of enablers and incentives in TB treatment is strongly encouraged. The Division of TB Control can offer guidance on appropriate techniques to be employed.



As programs utilizing Directly Observed Therapy (DOT) have the highest treatment completion rates, the use of DOT is strongly recommended in outpatient treatment.



Common obstacles to completing treatment include cultural and linguistic factors, lifestyle differences, and homelessness and substance abuse, that present priorities that compete with treatment for TB. Barriers may be patient-related, such as conflicting health beliefs, alcohol or drug dependence, or mental illness, or they may be system-related, such as lack of transportation, poor clinic hours, and lack of translators.

Reporting Process (§ 32.1-50.1.B & C)

A treatment plan is required for all patients with confirmed TB disease and those who are suspects. Whenever treatment has been started—even treatment based only on suspicion of active TB disease—a treatment plan must be in place. The treatment plan must be submitted to and approved by the local health director prior to discharge from any medical facility, correctional center, or other similar facility, even for patients who have suspected TB disease.

While a treatment plan should be developed for all patients with active TB disease, reporting requirements differ between outpatient and inpatient treatment:

OUTPATIENTTREATMENT

- For outpatient TB cases, the medical provider **may be requested** to submit the patient's written treatment plan to the local health director for approval.
- Submission of the treatment plan is required for all individuals receiving outpatient treatment who:
 - · Are HIV positive.
 - Have confirmed or suspected resistance to rifampin with or without resistance to any other drug.
 - Have a history of relapsed TB or prior treated or untreated TB.
 - Have a demonstrated history of non-adherence to a treatment regimen.

INPATIENTTREATMENT

- For inpatient TB cases, the person in charge of the medical facility (including correctional centers)—or his/her designee—is required to submit the written treatment plan to the local health director for approval in all cases, regardless of what other factors may or may not be present (e.g., HIV-positive status, drug-resistant TB, etc.).
- When there are changes to an inpatient's treatment plan, the revised treatment plan must be submitted to the local health director.
- The treatment plan must be approved by the local health director <u>prior to discharge</u>.

Requirements for Discharge

- For inpatients (or inmates) with diagnosed TB or TB not previously reported, the treatment plan must be submitted and approved by the local health director prior to discharge.
- For previously diagnosed inpatients (or inmates) who are known to the health department and whose treatment plans have not changed, the health department must be notified only of the impending discharge.

BOTH OUTPATIENT & INPATIENTTREATMENT

- Any patient being started on antituberculosis medications must have a treatment plan.
- The treatment plan is subject to approval by the local health director.
- Any disagreements between the written treatment plan and established standards of care will be addressed by the Commissioner.
- Documentation of adherence to the treatment plan will be submitted to the local health director, upon request.
- Any questions regarding this process should be directed to the Division of TB Control.



Emergency Detention Order Upon Discharge

The Commissioner may issue an emergency detention order for a person with active TB disease upon that person's release from an inpatient treatment facility or a state or local correctional or detention facility. This emergency detention order will be issued if the person with active TB disease indicates an unwillingness to comply with the prescribed treatment plan or exhibits noncompliant behavior. (§32.1-50.1.D)

Appendix

440

Forms for Physicians and Medical Facilities

- Physicians and Medical Facilities Summary
- Negative Diagnosis Form
- Initial TB Report (EPI-1)
- Secondary TB Report (2001A-TB-002)
- Subsequent TB Reports (2001A-TB-003)
- TB Treatment/Discharge Plan Template (2001A-TB-004)
- Notice of Discharge Letter

Summary of Individual Rights

Contact Information

Resource Listings

Forms for Physicians and Medical Facilities: Summary

This collection of forms is intended for use by physicians and medical facilities to communicate with the health director in accordance with the TB Control Laws outlined in the *Code of Virginia* and with reporting requirements set by the State Board of Health. All letters should be printed or typed on appropriate letterhead. A brief description and appropriate usage of each form is detailed below.

Negative Diagnosis Form (2001A-TB-000)

This form is to be completed and submitted to the local health director by the examining physician who makes a diagnosis other than active TB disease for a patient under an examination request.

Initial TB Report (EPI-1)

The initial TB report to the local health director is to be completed by the examining or treating physician or head of a medical facility providing inpatient or outpatient diagnosis or treatment when there are reasonable grounds to believe that a person has active TB disease.

Secondary TB Report (2001A-TB-002)

The secondary TB report to the local health director is to be completed by the examining or treating physician or head of a medical facility providing inpatient or outpatient diagnosis or treatment. This form is to be completed simultaneously with or immediately following the initial report.

Subsequent TB Reports (2001A-TB-003)

The subsequent TB report is to be completed when there has been a change in a patient's treatment regimen, if there is suspicion of treatment failure, when ceasing treatment for active TB disease, and/or when there are any other updates on the patient's case.

TB Treatment/ Discharge Plan Template (2001A-TB-004) This template is to be used by the treating physician or head of a medical facility providing inpatient or outpatient treatment for active TB disease to capture information which may be either requested or required by the local health director. This template may also be used to develop a patient's Discharge Plan, which must be submitted to and approved by the local health director prior to discharge.

TB Notice of Discharge Letter (2001A-TB-005) This form is to be used by the treating physician or head of a medical facility to communicate to the local health director that a patient with active TB disease – who was not hospitalized for his/her TB – is to be discharged from the hospital.

Forms for Physicians and Medical Facilities: Negative Diagnosis Form [2001A-TB-000]

Health Director Name Street Address City, Virginia ZIP code

Per your examination request, I have seen [Patient Name], who resides at [Patient's Full Address], and have rendered a thorough examination for tuberculosis disease.

[Documentation of Medical and Laboratory Tests and Other Examination Procedures Performed on This Patient.]

Given the above findings, it is my conclusion that [Patient Name] does not have active tuberculosis disease.

 It is my diagnosis that [Patient Name] has Latent TB Infection (LTBI).
 It is my diagnosis that [Patient Name] has disease due to Mycobacterium Other Than Tuberculosis (MOTT).
 [Other Diagnosis]

Dated on [Date]

[Signature and Printed Name of Examining Physician] [Physician Address] [Physician Telephone Number]

Forms for Physicians and Medical Facilities: Initial Report [EPI-1]

MAIL	THET	OP TWO COPIES TO	YOUR LOCA	L HEALT	H DEPARTM	ENT
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Patients Name	() ast, Float	Madic Infail.		SSN		
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				10000		
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Date of Diagnor	six.	Death. □ Yes □ No	Influen	en Report # 10	nd type only 140 paths	of identification)
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Please complete as much of this form as possible

From Tpin | 11/95

Forms for Physicians and Medical Facilities: Secondary Report [2001A-TB-002]

Tuberculosis Patient Information Sheet: Secondary Report

2001A-TB-002

Patient Last Nam						Uinet M	um or		
Address:									
									Weight;
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If foreign born, y						= 0			
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Initial CXR Date	:		Finding:			If Abno	ormal: Cav		
					bnormal			-cavitary	
Follow-up CXR					able □ In	proving		-	□ Not Done
Bacteriology (Iso						Collect	ion Date;		
Source:	☐ Sputum	☐ Ga	stric Aspira	te		Smear:		If Positi	ive, Quantity:
☐ Pleural Fluid	☐ Urine	\square Sp	nal Fluid				ive AFB	□ +/=	□ 3+
☐ Lung Tissue						☐ Nega	tive	□ 1+	□ 4+
☐ Lymph Node	Other:					□ Not I	Oone	□ 2+	□ Not Reported
Bacterial confirm	nation: 🗆 C	Culture	☐ Nuci	leic Ac	id Amplification	1			
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Forms for Physicians and Medical Facilities: Subsequent Report [2001A-TB-003]

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	r your care for TB;	If not, complete on Section 1 b	elow. If so,	skip to Section 2(a).
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Name:			Phor	ie:
Thank you for your assistance	e!			
Section 2(a)	**			
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□ Pleural Fluid □ Urine □ Lung Tissue □ Blood □ Lymph Node □ Other: □ Culture: □ M.tb □ N If the latest bacteriology is n Check here if anti-TB therap. If your patient is still on anti- assistance! Section 2(b) Check here if your patient is Notes on Patient's Adherence Current Therapy □ Dose/Fre □ Pyrazinamide □ Other, specify: □	Bronchial Wash Mycobacterium Other The gative on culture, date y has been completed: to TB therapy, please con currently taking anti-The to Treatment: equency Rifampin	ing Negative Note Done Negative Note Done Negative Neg	1+ 2+ Other, specify: egative culture: Form is complete. T If not, read **	4+ Not Reported hank you for your below. Dose/Frequency

Forms for Physicians and Medical Facilities: Treatment/Discharge Plan Template [2002A-TB-004]

TB Treatment/Discharge Plan

2002A-TB-004

Patient Name		Gender	ШΜ	۵F	DOB	SSN
Address						Telephone
Occupation		Work Sit	te			Work Phone
Emergency Contact		Address				Phone
	TO BE COMPLETED	BY THE	TRE	ATING	PHYSICIAN	OR FACILITY
Case reported to the local	d health department by:					on (date)
The TB care physicism w	will be:					
•						Phone
Other follow-up caregive	ers:(name, agency, & phone	- 1				
						on (date)
	eribed Patient body v					Completion of Therapy:
	ORIFmg OP		g		ßmg □ er	
	O other					
		2x weekly* (Devr)	,		-	is required for intermittent regimens
	☐ Directly Observed Therap	y(DOI)		LI Sti		perapy (SAT) DOT and SAT
1st DOT appointment:d	date time		place			HD staff 🗖 other:
Isolation Status:	☐ no isolation ☐ l	home isola	tion	□ kg	gal isolation	
Person monitoring isolat	tion:					
Identify any treatment ad	dherence obstacles:					
□ homelessness	☐ physical disability	□ s	abstanc	e abuse	:	
☐ mental disability	none		ther:_			
Identify any personal ser	rvice needs:					
☐ housing assistance	ce 🗆 food/nutrition		ocal/sta	te welf.	are 🗀 child o	are 🗆 transportation
drug treatment	🗆 mental health servi	ices 🗆 h	iome be	ahth ser	vices 🗆 emplo	yment services 🗆 none
O other:						
Referrals for these needs	s were/will be made to:					on (date)
Other considerations/con	nments:					
TO BE	COMPLETED BY THE	LHD A	VD PR	OVID	ED TO THE P	HYSICIAN/FACILITY
	alth Nurse Case Manager is:_					
	made by:					(name)
	lbe:					pt staff family member other
DOT will be done at				(addre	ss) 🗆 home	□ school □ work □ other
						agreement that includes DOT instructions.
•						
Other considerations/con	mments:					
			_	_		
	ls have been notified and appo	cove of the	above	treatme	mt plan:	
☐ Attending physician _						date
	ment					
	received instructions from my					
☐ Patient elected not to	sign: Discharge planner					date

Monitoring for Response to Treatment and Adverse Effects

This TB treatment check-list is provided for the treating physician and for the patient's reference. The outline below is merely a suggested monitoring plan for routine, trouble-free cases of active tuberculosis disease. Refer all questions to either the local health department or to the Division of Tuberculosis Control.

Baseline	Clinical evaluation with particular attention to:
Dasenne	I
	Co-morbid illnesses and medications
	 Risk factors for side effects and non adherence
	Chest x-ray (or other appropriate radiographs)
	HIV testing
	Specimens for AFB smear and culture (ideally 3)
	Arrange for susceptibility testing
	 CBC, renal, and liver profile – if abnormalities detected, investigate as appropriate (1)
	Other lab tests may be indicated for certain second line drugs
	Visual acuity with Snellen chart
	 Audiogram if prolonged aminoglycoside therapy is contemplated
	 Current medications: if patients are on other medications with known/suspected drug
	interaction, evaluation including levels or monitoring of these drugs is warranted
	Substance abuse
1 month	Clinical evaluation with particular attention to:
	Response to therapy
	Tolerance and adherence with therapy
	Sputum for AFB smear and culture (1)
	Liver transaminases if:
	Baseline abnormal,
	 Symptoms of side effects,
	 Age > 35,
	 Other known risk factors for drug induced hepatitis.
	 Visual acuity with Snellen chart - if ethambutol will be continued
	Other laboratory investigations if clinically indicated or on second line drugs
2 months	Clinical evaluation (as above)
	Sputum for AFB smear and culture (1)
	Chest x-ray (particularly if culture negative case)
	 Liver transaminases: if symptoms or other factors as for 1 month visit.
	Visual acuity with Snellen chart - if ethambutol will be continued
	 Other laboratory investigations if clinically indicated or on second line drugs
3 months	Clinical evaluation
	 Sputum for AFB smear and culture - if culture at one month was positive (1)
	Liver transaminases: if symptoms or other factors as for 1 month visit.
	Visual acuity with Snellen chart - if ethambutol will be continued
	Other laboratory investigations if clinically indicated or on second line drugs
1	and the second se

4 months	Clinical evaluation
	Sputum AFB smear and cultures
	 If 2-months culture positive
	 And/or 3-months culture positive
	 Visual acuity with Snellen chart - if ethambutol will be continued
	 Liver transaminases and other laboratory investigations prn
5 months	 Clinical evaluation, liver transaminases, and other laboratory tests if needed
	 Visual acuity with Snellen chart - if ethambutol will be continued
6 months	Clinical evaluation
	Chest x-ray
	 Visual acuity with Snellen chart - if ethambutol will be continued
Therapy	No specific follow-up is recommended
Follow-up	· It is very important to instruct patients to return at any time if symptoms suggestive of
- ээ.н	(reminiscent of) active TB recur

Notes:

- 1. In patients with epidemiologic risk factors, screening for hepatitis B and C is warranted.
- 2. It is important to demonstrate microbiologic conversion with two consecutive negative sputum cultures.

Forms for Physicians and Medical Facilities: Notice of Discharge Letter [2001A-TB-005]

Health Director Name Health Department Address City, VA ZIP Code

Per the regulations set forth by the State Board of Health, I am notifying the health department that [Patient Name] is due to be discharged from [Hospital Name or Name of Medical Facility] on [Intended Discharge Date].

While [Patient Name] is currently undergoing treatment for active tuberculosis disease, tuberculosis treatment was not the reason for this hospitalization. The tuberculosis treatment plan for [Patient Name] is on file and will be submitted upon request.

Dated on [Date]

[Signature and Printed Name of Treating Physician or Head of Medical Facility]
[Address]
[Telephone Number]

Summary of Individual Rights

A person who has either suspected or confirmed active TB disease has the following rights:

- A person will not be physically forced to swallow medication.
- All warnings and orders will be in a language the person can understand.
- Any action (e.g., an examination request or order for treatment) will be supported by proper documentation.
- A person subject to a court order has the right to appeal.
- If ordered to appear before the court, the person shall be informed of his/her right to representation by counsel.
- A person who cannot afford legal counsel will have it provided for him or her.
- Neither the Commissioner nor any local health director shall disclose to the public the name of any person reported.

Division of TB Control Contact Information

Division of TB Control 1500 East Main Street Room 119 Richmond, VA 23219 telephone: 804-786-6251

fax: 804-371-0248

url: www.vdh.state.va.us/epi/tb/

Resources

The complete code of the Virginia TB Control Laws can be viewed online:

§ 32.1-48.01	Definitions. http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-48.01
§ 32.1-48.02	Investigations of verified reports or medical evidence; counseling; outpatient and emergency treatment orders; custody upon emergency order. http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-48.02
§ 32.1-48.03	Petition for hearing; temporary detention. http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-48.03
§ 32.1-48.04	Isolation hearing; conditions; order for isolation; right to appeal. http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-48.04
§ 32.1-49.1	Definitions http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-49.1
§ 32.1-50	Examination of persons suspected of having active tuberculosis disease; reporting; report forms; report schedule; laboratory reports and required samples. http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-50
§ 32.1-50.1	Treatment plan; submission of plan and mediation of disagreements; determination of cure. http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-50.1

The complete *Code of Virginia* is available online: http://legis.state.va.us/codecomm/codehome.htm

The Commonwealth of Virginia State Board of Health Regulations for Disease Reporting and Control web resource: www.vdh.state.va.us/epi/regcover.htm

Centers for Disease Control Division of Tuberculosis Elimination website: http://www.cdc.gov/nchstp/tb/

The Division of TB Control websites:

- external: http://www.vdh.state.va.us/epi/tb/
- internal: http://vdhweb/epi/tb/

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VIRGINIA DEPARTMENT OF HEALTH Protecting You and Your Environment www.vdh.state.va.us



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